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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10-024,199	12-21-2001	Claudio De Simone	2818-72	4379

7590

12-17-2002

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EXAMINER

WARE, DEBORAH K

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/17/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/024,199

Applicant(s)
Simone

Examiner
Deborah Ware

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 2, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

Claims 1-11 and 15-22 are presented for reconsideration on the merits.

The amendment file October 2, 2002, and declaration for deposit have been received and entered of record. Claims 12-14 have been canceled pursuant the amendment. Applicants' foreign priority is also acknowledged and appropriate papers have been received.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11 and 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rendered vague and indefinite for failing to set forth proper antecedent basis for "component a" and "component b" in all pertinent claims where the phrases are used after their first use in claims 1 and 19. The terms --said first-- and --said second-- for each of the successive repeated recitations of "component a" and "component b" at all appropriate occurrences in the claims, the terms as noted above should be inserted before each successive repeated occurrence throughout the claims to remedy this problem.

Claims 19-22 are further rendered vague and indefinite for the recitation of "of prophylaxis or treating infectious" which should be changed to --of prophylaxis for treating infections-- . Most likely the recitation was a typo based upon a reading of the other dependent claims. Further, the claim 19 remains unclear with respect to failing to

recite clear and distinct process steps for administering a combination of lactic acid bacteria because it is not clear to what or how such administering is being carried out?

Claims 1-11 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Cavaliere Ved. Vesely et al. (A) in view of newly cited Ehret (B).

Claims are drawn to a combination of lactic acid bacteria and method of using for treating infections or inflammatory conditions.

Cavaliere Ved. Vesely et al. (Vesely) teach a lactic acid combination which can be *Lactobacillus brevis* and *Lactobacillus salivarius*. See the abstract. The combination may be combined in various ratios and concentrations. Note col. 4, lines 10-15. At least one of the strains must have capability of producing hydrogen peroxide. Note col. 3, lines 1-15. Further, disclosed in the background art at col. 2, lines 20-30, is that various *Lactobacilli* have been used including *L. crispatus*, *L. gasseri*, *L. casei*, *L. fermentum*, etc. Further disclosed is the combination in the form of a pharmaceutical for treatment of infections such as vaginal infections. Note col. 4-5, all lines.

Ehret teaches *L. brevis* utilizes arginine. See in Table 3, in col. 8, line 61 wherein the reaction was positive for arginine.

The claims differ from Vesely in that utilization of arginine is not disclosed

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use in the combination of Vesely the *L. brevis* strain disclosed by Ehret in order to provide for a combination of the two type of *lactobacilli* which can produce hydrogen peroxide and utilize arginine. Vesely clearly teaches the

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treatment of infections using such combinations. To select for a lactic acid bacterium which utilizes arginine is clearly an obvious modification. This is especially true since the claimed composition is also desired to be administered orally and the arginine utilizing *L. brevis* of Ehret is disclosed to be useful in food applications. Note col. 1, line 24. One of ordinary skill in the art would have expected successful results with the combination as set forth by the Vesely and Ehret references.

The concentrations are clearly disclosed in the reference as indicated above and to vary their ratios in the composition for use in treating infections is an obvious modification as well and within the purview of an ordinary artisan. The composition is disclosed by Vesely to be applied to the vagina as an anti-inflammatory. Furthermore, to include other lactic acid producing bacteria is also clearly disclosed by the cited prior art. Formulating the composition for oral administration is clearly within the purview of an ordinary artisan and is suggested by the cited prior art combination. The combination is clearly taught by the cited prior art and one of skill would have been motivated to formulate this combination as claimed herein. In the absence of persuasive evidence to the contrary the claims are deemed *prima facie* obvious.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 16 and 19-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S.

Patent No. 6,277,370 (Vesely as cited above) in view of Ehret.

The claims are discussed above.

Vesely claim a composition of lactobacilli and treatment of infections. The composition can be of the same combination as claimed herein: *L. brevis* and *L. salivarius*.

Ehret is discussed above.

It would have been obvious to one of ordinary skill in the art based upon a reading of Vesely's claims to provide for the claimed composition. To select for a specific strain of *L. brevis* is further an obvious modification of the cited prior art. As discussed above concentrations and ratios are clearly taught, or at least suggested in terms of the ratios, in the cited prior art. Further, to select for various species of lactobacilli. Clearly one of skill would have been motivated by these patented claims to provide for a composition as claimed. Ehret clearly teaches that *L. brevis* utilizes arginine. Thus, to select for this microorganism for use in the combination is an obvious modification of the prior art. *L. brevis* is well recognized as taught by Vesely and to provide for an arginine utilizing *L. brevis* is within the skill of an ordinary artisan. The claims are prima facie obvious over the cited references.

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All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed.

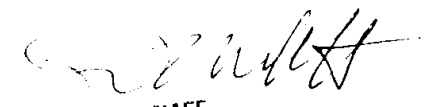
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications and 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.



Deborah K. Ware
December 16, 2002



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651